

Certificate of Analysis

Productname: Xylometazolini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-186517B
Batchnumber: 19B07-B02-371989
Reference code / No.: 3661 / 18162024
Analysed according to: PH.EUR 9.7

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear / <=Y6	Conform		5% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	0,05	%	
Unspecified impurities	<=0,10 <i>elk</i>	0,05	%	
Total impurities	<=0,5	0,0	%	
Loss on drying	<=0,5	0,1	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Xylometazoline hydrochloride	99,0 - 101,0	100,2	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

10/22/20

Expiration: 04-2023

Conclusion: APPROVED

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